

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 084437-0169
INTERNATIONAL APPLICATION NO. PCT/JP2004/019767	INTERNATIONAL FILING DATE 12/24/2004	U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 10/584,242
TITLE OF INVENTION METHOD OF IMPROVING SUITABILITY FOR GRANULATION		PRIORITY DATE CLAIMED 12/25/2003
APPLICANT(S) FOR DO/EO/US Yusuke MURAKAWA et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 20px;"><input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;"><input type="checkbox"/> has been communicated by the International Bureau.</p> <p style="margin-left: 20px;"><input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 20px;"><input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 20px;"><input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 20px;"><input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau).</p> <p style="margin-left: 20px;"><input type="checkbox"/> have been communicated by the International Bureau.</p> <p style="margin-left: 20px;"><input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;"><input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
Items 11 to 20 below concern other document(s) or information included:		
<p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input type="checkbox"/> Other items or information:</p>		

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/584,242		INTERNATIONAL APPLICATION NO. PCT/JP2004/019767		ATTORNEY'S DOCKET NUMBER 084437-0169	
The following fees have been submitted:					
21. <input checked="" type="checkbox"/>	Basic national fee			\$300	\$ 300.00
22. <input checked="" type="checkbox"/>	Examination fee				
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)				\$100	\$ 200.00
All other situations				\$200	
23. <input checked="" type="checkbox"/>	Search fee				
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority				\$100	
International Search Report prepared and provided to the Office				\$400	
All other situations				\$500	\$ 400.00
TOTAL OF ABOVE 21, 22 and 23 =					\$ 900.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$ for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		RATE	
27	- 100 = 0	/50 = 0		x \$250.00	\$ 0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))					\$ 0.00
CLAIMS		NUMBER FILED	NUMBER EXTRA	RATE	\$
Total Claims		17 - 20 = 0		x \$ 50.00	\$ 0.00
Independent Claims		4 - 3 = 1		x \$ 200.00	\$ 200.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$ 360.00	\$
TOTAL OF ABOVE CALCULATIONS =					\$ 1100.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					\$ 0.00
SUBTOTAL =					\$ 1100.00
Processing fee of 130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					\$
TOTAL NATIONAL FEE =					\$ 1100.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). 40.00 per property					\$
TOTAL FEES PREVIOUSLY PAID =					\$ 1100.00
					Amount to be refunded:
					charged:
<p>a. <input type="checkbox"/> A check in the amount of _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. <u>19-0741</u> in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-0741</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charge to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
<p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p>					
SEND ALL CORRESPONDENCE TO:					
Foley & Lardner LLP				SIGNATURE	
Customer Number: 22428				Stephen B. Maebius	
				NAME	
				35,264	
				REGISTRATION NUMBER	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yusuke MURAKAWA et al.
Title: METHOD OF IMPROVING SUITABILITY
FOR GRANULATION
Appl. No.: 10/584,242
International Filing Date: 12/24/2004
371(c) Date: 6/23/06
Examiner: Unassigned
Art Unit: Unassigned
Conf. No.: 1685

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

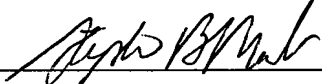
English abstracts are now provided for JP 2001-335469 and JP 2003-160474, both previously cited. An English abstract is on the first page of WO 02/078673.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date SEP 22 2006

By 

FOLEY & LARDNER LLP
Customer Number: 22428
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Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: SEP 22 2006 <i>(use as many sheets as necessary)</i>		Complete if Known	
Application Number		10/584,242	
Filing Date		12/24/2004	
First Named Inventor		Yusuke MURAKAWA	
Group Art Unit		Unassigned	
Examiner Name		Unassigned	
Attorney Docket Number		084437-0169	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B1	JP	2001-335469	A	Lion Corp.	12/04/2001		A
	B2	JP	2003-160474	A	Taisho Pharmaceut Co Ltd	06/03/2003		A
	B3	WO	99/47125	A1	Andrx Pharmaceuticals Inc	09/23/1999		
	B4	WO	02/078673	A1	Takeda Chemical Industries, Ltd.	10/10/2002		A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	B5	LERK et al., "Application of sucrose laurate, a new pharmaceutical excipient, in peroral formulations of cyclosporin A," International Journal of Pharmaceutics, vol. 92, 1993, pp. 197-202.	
	B6	RUDDY et al., "Design and characterization of a surfactant-enriched tablet formulation for oral delivery of a poorly water-soluble immunosuppressive agent," International Journal of Pharmaceutics, vol. 182, 1999, pp. 173-186.	

Examiner Signature	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.